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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,653	09/03/2003	Daniel J. Cook	14/1454US	8300

22822 7590 11/20/2009

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SUITE 2000

ST LOUIS, MO 63102

EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

11/20/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.		Applicant(s)	
	10/656,653		COOK, DANIEL J.	
	Examiner		Art Unit	
	Darwin P. Erez		3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-17, 20-27, 30-39 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7-17, 20-26, 30-33 and 45-47 is/are allowed.
- 6) ☒ Claim(s) 27, 34-39 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 7/13/09.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 27, 34 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 27 recites the limitation of "the rear portion of the positioning shield" in line 13. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests amending the second paragraph of the claim to include the limitation of the inflatable positioning shield having "a rear portion formed between the [a] posterior base and the peripheral portion", similar to that of independent claim 1 or 30.

5. Claim 34 recites the limitation "the perimeter of the lumen formed by the distal end of the respiratory tube which passes through the peripheral portion of the positioning shield" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 48 is dependent upon cancelled claim 43, thus rendering claim 48 indefinite. Claim 48 should also be cancelled.

Claim Rejections - 35 USC § 102

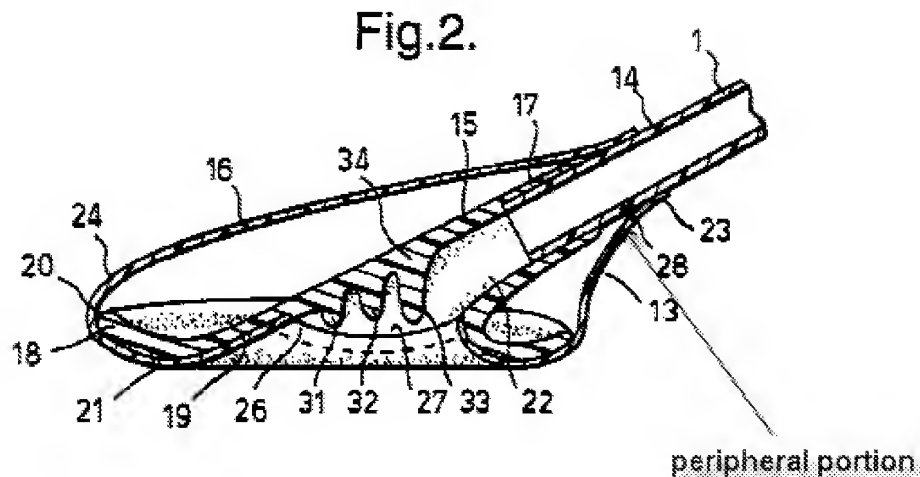
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 34, 35, 37 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,240,922 to Pagan.

Pagan teaches a laryngeal mask comprising horizontal runners 31-33 or the deflector shown in Fig. 6, which is viewed as a means for elevating an epiglottis and surrounds a portion of the perimeter of the lumen and does not obstruct the lumen (the lumen is not obstructed/closed). Pagan also discloses a respiratory tube passing through a peripheral portion of a positioning shield (as seen below), wherein the distal end of the respiratory tube also passes through a rear portion; wherein the respiratory tube is circular and flexible.



It is also noted that the Pagan reference qualifies as a prior art because the structure of the horizontal rib is not present in any of the parent cases.

It is further noted that the means plus function limitation in claim 34 does not properly invoke 35 USC 112, sixth paragraph because the means is modified by sufficient structure (surrounding a portion of the perimeter of the lumen formed by the distal end of the respiratory tube) for achieving the specified function.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pagan in view of US 5,682,880 to Brain.

Pagan discloses all the limitations of the claim except for the respiratory tube having an oval cross-section. However, the use of a respiratory tube having an oval cross-section in a laryngeal mask is well known in the art. For instance, Brain discloses a respiratory tube having an oval cross-section with an endotracheal tube located within (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the respiratory tube of Pagan to that of Brain because it allows an oval/elliptical endotracheal tube to be used and inserted into the respiratory tube and laryngeal mask with little difficulty.

12. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pagan in view of US Re. 35,531 to Callaghan et al.

Pagan discloses all the limitations of the claim except for the respiratory tube having more than one lumen. However, Callaghan discloses that it is well known in the art to use a respiratory tube having more than one lumen 27. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

modify the device of Pagan to also have multiple lumens as it would allow respiratory air to reach the patient even if one of the lumens is accidentally blocked.

Allowable Subject Matter

13. Claims 1-5, 7-17, 20-26, 30-33 and 45-47 are allowed over the prior art of record

14. Claim 27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

15. Applicant's arguments regarding claim 34 have been fully considered but they are not persuasive. The rejections above have been modified to cover the newly added limitations for the independent claim. Note that Pagan discloses a peripheral portion in which the respiratory passes through since the limitation of a "peripheral portion" is broader in this claim than the allowed claims above.

16. Applicant's arguments with respect to claims 35-39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezó whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezó/
Primary Examiner, Art Unit 3773